

CLAIMS

1. A process for the preparation of sertraline hydrochloride by
 - a. Suspending/dissolving sertraline acetate in suitable solvents
 - 5 b. Adjusting the pH of the mixture with hydrogen chloride either in anhydrous form or aqueous form at elevated temperatures ranging from 25°C to 65°C
 - c. Cooling the reaction mixture
 - d. isolating and drying to obtain sertraline hydrochloride.
- 10 2. A process according to claim 1, wherein in step b, the pH of the mixture is adjusted with hydrogen chloride gas at elevated temperatures ranging from 40°C to 65°C; in step c, the reaction mixture is cooled gradually over more than 2 hours to bring the temperature to 25°C-20°C; and in step d, the sertraline hydrochloride obtained is
15 sertraline hydrochloride form II.
3. A process according to claim 1, wherein in step b, the pH of the mixture is adjusted with hydrogen chloride gas at elevated temperatures ranging between 40°C to 65°C; in step c, the reaction mixture is cooled rapidly in less than 30 minutes to bring
20 the temperature to 15°C to 20°C; and in step d, the sertraline hydrochloride obtained is sertraline hydrochloride form III.
4. A process according to claim 3, wherein the cooling is done rapidly over a few minutes.
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5. A process according to claim 1, wherein in step b, the pH of the mixture is adjusted with hydrogen chloride gas at elevated temperatures ranging between 40°C to 65°C; in step c, the reaction mixture is cooled rapidly in less than 30 minutes to bring the temperature to 15°C to 25°C; and in step d, the drying is carried out in a fluid bed
30 drier, and the sertraline hydrochloride obtained is sertraline hydrochloride form IV.
6. A process according to claim 5, wherein the sertraline acetate is suspended/dissolved in solvents such as methanol, ethanol, isopropanol, ethyl acetate,

or mixtures thereof.

7. A process according to claim 5 or 6, wherein the solvent used is isopropanol.
- 5 8. A process according any one of claims 2 to 4, wherein the sertraline acetate is
suspended/dissolved in solvents such as methanol, ethanol, isopropanol, ethyl acetate,
toluene or mixtures thereof.
9. A process according to any one of claims 2 to 4, wherein the solvent used is a
10 mixture of isopropanol and toluene.
10. A process according to claim 9, wherein toluene is present between 2 to 8% by
weight of the total volume of solvent.
- 15 11. A process according to any of claims 2 to 10, wherein the pH of the mixture is
adjusted to a value from 1- 2.
12. A process according to claim 11, wherein the pH is adjusted at a temperature
from 45°C to 65°C.
- 20 13. A process according to claim 1, wherein in step b, the pH of the mixture is
adjusted with aqueous hydrochloric acid at ambient temperatures ranging between
25°C and 35°C; and in step d, the sertraline hydrochloride obtained is sertraline
hydrochloride form V.
- 25 14. A process according to claim 13, wherein the sertraline acetate is
suspended/dissolved in solvents such as methanol, ethanol, isopropanol, ethyl acetate,
water or mixtures thereof.
- 30 15. A process according to claim 13, wherein the solvent used is water.
16. A process according to claim 13, 14 or 15, wherein the pH of the mixture is
adjusted to a value from 1-2.

17. A process for the preparation of sertraline hydrochloride Form V by
- Suspending/dissolving sertraline base in acetic acid
 - Adjusting the pH of the mixture with aqueous hydrogen chloride
 - Cooling the reaction mixture
 - Isolating and drying the sertraline hydrochloride to obtain form V.
18. A process according to claim 17, wherein the pH of the mixture is adjusted to a value from 1-2.
19. A process according to claim 17 or 18, wherein the cooling is done gradually to bring the temperature from 30°C to 5°C - 0°C.
20. Sertraline hydrochloride produced by a process according to any one of claims 1 to 19.
21. Form II sertraline hydrochloride produced by a process according to any one of claims 2 or 8 to 12.
22. Form III sertraline hydrochloride produced by a process according to any one of claims 3, 4 or 8 to 12.
23. Form IV sertraline hydrochloride produced by a process according to any one of claims 5 to 7, 11 or 12.
24. Form V sertraline hydrochloride produced by a process according to any one of claims 13 to 19.
25. A pharmaceutical composition comprising sertraline hydrochloride according to claim 20 in combination with a pharmaceutically acceptable carrier.
26. A pharmaceutical composition comprising sertraline hydrochloride Form II according to claim 21 in combination with a pharmaceutically acceptable carrier.

27. A pharmaceutical composition comprising sertraline hydrochloride Form III according to claim 22 in combination with a pharmaceutically acceptable carrier.

5 28. A pharmaceutical composition comprising sertraline hydrochloride Form IV according to claim 23 in combination with a pharmaceutically acceptable carrier.

29. A pharmaceutical composition comprising sertraline hydrochloride Form V according to claim 24 in combination with a pharmaceutically acceptable carrier.